fractions for 5 days a week. Toxicity was recorded using the CTCAE v4.0 to define a Dose Limiting Toxicity (DLT) and a Maximum Tolerated Dose (MTD) of MTL005.

Results: A total of 8 patients, 7 males (88%) and 1 female (12%), were enrolled, 4 in each of the 2 dose level cohorts. Six patients, all male with median age of 65 (54-77), were dosed with MTL005 successfully, 3 in each cohort. Dosing failures were due to an unexpected severe pain reaction (1 patient) and a technical problem with the infusion line (1 patient). In the 6 evaluable patients the following adverse events were recorded. Grade ≤2 oral mucositis and dysphagia were recorded in 3 (50%) and 4 (67%) patients respectively. Grade 1 pain in site of MTL005 injection was assessed in 1 (17%) patient. Grade ≤2 other toxicities (anaemia, dysgeusia) occurred in 3 (50%) patients. Grade 3 (dyspnoea, pneumonitis, oral haemorrhage, back pain, hyperuricemia) and Grade 4 toxicity (sepsis) were recorded in 4 (67%) and 1 (17%) cases respectively requiring hospitalisation and being considered as Serious Adverse Events (SAE). None of the SAE was assessed as directly related to MTL005 so DLT/MTD was not defined.

Conclusion: We completed Part 1 of the study and MTL005 DLT/MTD was not defined. Part 2 has been commenced with a MTL005 starting dose of 4mg/kg and is currently ongoing.

EP-1049

Prognostic role of 18F-FDG PET/CT in head and neck cancers treated with radical radio-chemotherapy

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Purpose or Objective: To assess the prognostic role of 18F - FDG PET/CT based response evaluation after primary concomitant radio-chemotherapy (RCT) for loco regionally advanced Head and Neck squamous cell carcinoma (HNSCC).

Material and Methods: 150 patients were included in this retrospective study. Mean age was 59 years (107 males and 43 females). The sites of HNSCC were oropharynx (53%), nasopharynx (14%), oral cavity (10%), hypopharynx (7%), larynx (7%), salivary glands (5%) and paranasal sinuses (4%). All patients underwent 18F-FDG PET/CT between 2006 and 2013 to assess treatment response; 62% of patients also had a pre-therapy 18F -FDG PET/CT scan. 18F -FDG PET/CT was performed from 6 to 36 weeks (median 21 weeks) after the end of RCT. Patients were divided in three groups: 18F -FDG PET/CT performed from 6 to 14 weeks after the end of RCT (group I: 30 patients), from 15 to 23 weeks (group II: 89 patients) and from 24 to 36 weeks (group III: 31 patients). 18F -FDG PET/CT scans were performed according to standard procedure, then they were visually analysed by 2 expert physicians and categorized as negative ("score 1"), doubt negative ("score 2"), doubt positive ("score 3") and positive ("score 4"). Patients were followed-up, based on clinic and radiological and/or histological findings. Median follow up was 38 months (range, 12-60 months). At the end of the follow-up 18F-FDG PET/CT were classified as true positive (TP), true negative (TN), false positive (FP) and false negative (FN).

Results: Group I showed "score 1" in 14 patients, "score 4" in 11 patients and therefore 18F-FDG PET/CT sensitivity was 69%, specificity 83%, VPP 82%, VPN 72%, and accuracy 0.76. This group showed 5 doubt scans (16%) as "score 2" that were find out to be 2 negatives and 3 positives. No "score 3" was observed in this group. Group II showed "score 1" in 55 patients, "score 4" in 27 patients and therefore 18F-FDG PET/CT sensitivity was 87%, specificity 98%, VPP 96%, VPN 93%, and accuracy 0.94. This group showed 7 (8%) doubt scans: 3 scans (3.5%) as "score 2" that in follow-up were 1 negative and 2 positives and 4 scans (4.5%) as "score 3" that were found out to be 2 negatives and 2 positives. Group III showed "score 1" in 24 patients and "score 4" in 6 patients and therefore 18F-FDG PET/CT sensitivity was 86%, specificity 100%, VPP 100%, VPN 96%, and accuracy 0.97. This group showed only 1 doubt scan (3%) as "score 2" that was find out to be negative.

Conclusion: According to our data, PET/CT with 18F-FDG showed an excellent prognostic value of treatment response to primary concomitant RCT if performed at least 14 weeks after the end of RCT. We also observed that the numbers of "doubt scans" significantly decrease 14 weeks after the end of RCT.

EP-1050

Volume definition in radiotherapy planning for thyroid cancer: a retrospective observational study

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Purpose or Objective: The role of post-operative external beam radiotherapy (EBRT) in differentiated thyroid carcinomas is still discussed considering the low clinical aggressiveness and the possibility to perform a radioiodine ablation (RAI). However, there are dedifferentiated tumors that, over time, lose their capacity to capture Iodine. The aim of this study is to evaluate the utility of 18F-FDG PET/CT in volumes defining and the clinical response rate after EBRT in these patients.

Material and Methods: Patients with locally recurrent thyroid cancer, treated with radical EBRT from October 2011 to March 2015 after total thyroidectomy and RAI, were included in the study. When EBRT was planned, thyroglobulin (HTG) was detectable and there was negative post-RAI whole body scintigraphy (WBS) and no surgical indications. All patients underwent a pre-treatment 18F-FDG PET/CT that resulted positive: 3 in loggia, 3 in loggia and lymph nodes, 9 in lymph nodes, 1 in lymph nodes and in lung. EBRT was delivered with IMRT-SIB technique: a dose of 66 Gy (2.2 Gy/fr) to increased FDG-uptake areas, 60 Gy (2 Gy/fr) to ipsilateral lymph nodes and 54 Gy (1.8 Gy/fr) to contralateral ones, in 30 fractions, 1 fr/die. A revaluation 18F-FDG PET/CT and HTG dosage during the follow-up (range: 5-43 months) was performed. Acute and late toxicity were assessed with CTCAE v. 4.03 and EORTC-RTOG scales respectively, the metabolic, clinical and instrumental response with PERCIST and RECIST criteria. Local control (LC) and overall survival (OS) were analysed with Kaplan-Meier method.

Results: Sixteen patients were treated and analyzed consecutively [M / F: 8/8; median age: 71 years; range: 36-81; histology: 15 papillary carcinomas and 1 follicular carcinoma; UICC stage: III-IV]. Post-EBRT 18F-FDG PET/CT showed CR in 7 (43.8%), PR in 5 (31.2%), SD in 4 (25.0%) patients and unknown lung metastases in 2 patients (12.5%). HTG decreased in agreement with PET/CT results. 4 patients (25.0%) had G3 skin acute toxicity and no one showed G4 late toxicity. LC and OS rates were 100% at last follow-up (median F-UP: 12.3 months).